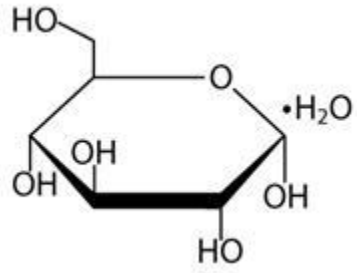
DELFLEX NEUTRAL PH - dextrose monohydrate, sodium chloride, calcium chloride, magnesium chloride and sodium lactate injection, solution
Fresenius Medical Care North America

PATIENT PACKAGE INSERT
DELFLEX® Neutral pH
Peritoneal Dialysis Solution
For Intraperitoneal Administration Only

89-905-66 Rev. 09/09
No Latex

DESCRIPTION

DELFLEX® Neutral pH peritoneal dialysis solutions, (standard, low magnesium and low magnesium/low calcium) are sterile, non-pyrogenic formulations of dextrose and electrolytes in water for injection, USP, for use in peritoneal dialysis. In comparison to conventional peritoneal dialysis solutions, *DELFLEX® Neutral pH* solutions are formulated to lower levels of glucose degradation products and provide a neutral pH of 7.0 ± 0.4, which is closer to the physiologic pH. The osmotic and buffer solutions are stored separately and mixed by the patient prior to use. Composition, calculated osmolarity, pH and ionic concentrations of the mixed solutions are shown in Table 2.
D-glucose monohydrate ($C_6H_{12}O_6 \cdot H_2O$) is a hexose sugar freely soluble in water. It has the following structural formula:



Calcium Chloride, USP, is chemically designated calcium chloride dihydrate ($CaCl_2 \cdot 2H_2O$) white fragments or granules freely soluble in water.
Magnesium Chloride, USP, is chemically designated magnesium chloride hexahydrate ($MgCl_2 \cdot 6H_2O$) colorless flakes or crystals very soluble in water.
Sodium lactate solution, USP, is chemically designated $CH_3CH(OH)COONa$, a 60% aqueous solution miscible in water.
Sodium chloride, USP, is chemically designated NaCI, a white, crystalline compound freely soluble in water.
Water for injection, USP, is chemically designated H_2O.
Hydrochloric acid, and sodium hydroxide may be added for pH adjustment. pH is 7.0 ± 0.4.
Since the flexible inner bag is compounded from a specific polyvinyl chloride, water may permeate from the inner bag into the outerwrap in quantities insufficient to affect the solution significantly. Solutions in contact with the plastic inner bag can cause certain chemical components of the bag to leach out in very small amounts; however, the safety of the plastic formulation is supported by biological tests for plastic containers.
Nominal glucose degradation product (GDP) levels (immediately following sterilization) in DELFLEX Neutral pH solution and DELFLEX solution are reported in Table 1. The clinical relevance of these differences in GDP levels is unknown.

Table 1. Glucose Degradation Product Levels*

Dextrose Concentration	DELFLEX ® Neutral pH	DELFLEX®
1.5%	23	267
2.5%	51	362
4.25%	106	437

*This is the sum (μmol/L) of the various component GDPs including: formaldehyde, acetaldehyde, furaldehyde, glyoxal, methylglyoxal, 5-hydroxymethylfurfural (5-HMF), and 3-deoxyglucosone (3DG).

Composition, Calculated Osmolarity, pH, and Ionic Concentration

Table 2. 3 Liter DELFLEX®Neutral pH

		Standard Magnesium, Standard Calcium			Low Magnesium, Standard Calcium			Low Magnesium, Low Calcium		
		1.5% Dextrose	2.5% Dextrose	4.25% Dextrose	1.5% Dextrose	2.5% Dextrose	4.25% Dextrose	1.5% Dextrose	2.5% Dextrose	4.25% Dextrose
Composition / 100ml	Main Bag Contents									
	Dextrose Hydrous, USP ($C_6H_{12}O_6$• H_2O)	1.52 g	2.54 g	4.32g	1.52g	2.54 g	4.32g	1.52g	2.54g	4.32g
	Sodium Chloride, USP (NaCl)	576mg	576 mg	576 mg	547mg	547 mg	547 mg	547 mg	547 mg	547mg
	Calcium Chloride, USP ($CaCl_2$• $2H_2O$)	26.1mg	26.1mg	26.1mg	26.1mg	26.1mg	26.1mg	18.7mg	18.7mg	18.7mg
	Magnesium Chloride, USP ($MgCl_2$ • $6H_2O$)	15.4mg	15.4mg	15.4mg	5.16mg	5.16mg	5.16mg	5.16mg	5.16mg	5.16mg
	Mini-bag Contents									
	Sodium Lactate($C_3H_5NaO_3$)	21.6 mg	21.6mg	21.6mg	25.0mg	25.0mg	25.0 mg	25.0mg	25.0 mg	25.0 mg
	Sodium Bicarbonate($NaHCO_3$)	1.80 g	1.80g	1.80 g	1.80g	1.80g	1.80g	1.80g	1.80g	1.80g
	Total ingredient content AFTER mixing Main Bag and Mini-bag solutions									
	Dextrose Hydrous, USP ($C_6H_{12}O_6$• H_2O)	1.5g	2.5g	4.25g	1.5g	2.5g	4.25g	1.5g	2.5g	4.25g
	Sodium Chloride, USP (NaCl)	567mg	567mg	567mg	538mg	538mg	538mg	538mg	538mg	538mg
	Sodium Lactate($C_3H_5NaO_3$)	353mg	353mg	353mg	409mg	409mg	409mg	409mg	409mg	409mg
	Sodium Bicarbonate($NaHCO_3$)	29.4mg	29.4mg	29.4mg	29.4mg	29.4mg	29.4mg	29.4mg	29.4mg	29.4mg
	Calcium Chloride, USP ($CaCl_2$• $2H_2O$)	25.7 mg	25.7 mg	25.7 mg	25.7 mg	25.7 mg	25.7 mg	18.4 mg	18.4 mg	18.4 mg
	Magnesium Chloride, USP ($MgCl_2$ • $6H_2O$)	15.2 mg	15.2 mg	15.2 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg
Osmolarity(mOsmoL/L)(calc)		347	398	486	346	396	485	344	394	483
pH 7.0 ± 0.4		7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0

Main Bag Contents

Ionic Composition(mEq/L)	Sodium	98.6	98.6	98.6	93.5	93.5	93.5	93.5	93.5	93.5
	Calcium	3.56	3.56	3.56	3.56	3.56	3.56	2.54	2.54	2.54
	Magnesium	1.52	1.52	1.52	0.51	0.51	0.51	0.51	0.51	0.51
	Chloride	104	104	104	97.6	97.6	97.6	96.6	96.6	96.6
	Mini-bag Contents									
	Sodium	2142	2142	2142	2448	2448	2448	2448	2448	2448
	Lactate	1927	1927	1927	2233	2233	2233	2233	2233	2233
	Bicarbonate	214	214	214	214	214	214	214	214	214
	Main Bag and Mini-bag Contents Combined									
	Sodium	132	132	132	132	132	132	132	132	132
	Calcium	3.5	3.5	3.5	3.5	3.5	3.5	2.5	2.5	2.5
	Magnesium	1.5	1.5	1.5	0.5	0.5	0.5	0.5	0.5	0.5
	Chloride	102	102	102	96	96	96	95	95	95
	Lactate	31.5	31.5	31.5	36.5	36.5	36.5	36.5	36.5	36.5
	Bicarbonate	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5

CLINICAL PHARMACOLOGY

Peritoneal dialysis is the process of filtering excess water and toxins from the bloodstream through a semi-permeable membrane. This process does not cure the disease, but prevents progression of symptoms. Dialysis for chronic kidney failure is essential to maintain life, unless the patient receives a kidney transplant. A peritoneal dialysis procedure utilizes the peritoneum (lining of the abdomen) as the semi-permeable membrane. The procedure is conducted by instilling peritoneal dialysis solution through a catheter in the abdomen into the peritoneal cavity. Since the peritoneum is heavily supplied with blood vessels, the contact of the solution with the peritoneum causes excess water and toxins in the bloodstream to be drawn across the membrane into the solution. This osmosis and diffusion occurs between the plasma of the patient and the peritoneal dialysis solution. After a period of time called “dwell time,” the solution is then drained from the patient.

This solution does not contain potassium. In situations in which there is a normal serum potassium level or hypokalemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) may be indicated to prevent severe hypokalemia. Addition of potassium chloride should be made after careful evaluation of serum and total body potassium and only under the direction of a physician.

Clinical studies have demonstrated that the use of low magnesium solutions resulted in significant increases in serum CO_2 and decreases in serum magnesium levels. The decrease in magnesium levels did not cause clinically significant hypomagnesemia.

INDICATIONS AND USAGE

DELFLEX® peritoneal dialysis solutions are indicated in the treatment of chronic renal failure patients being maintained on peritoneal dialysis when nondialytic medical therapy is judged to be inadequate.

CONTRAINDICATIONS

None Known

WARNINGS

Not for Intravenous injection.

Use Aseptic Technique.

It is important to mix the buffer (mini-bag) and main solutions thoroughly. Administer within 24 hours after mixing. Once solutions are mixed, medication may be added prior to administration.

Peritoneal dialysis should be done with great care, in patients with a number of conditions, including disruption of the peritoneal membrane or diaphragm by surgery or trauma, extensive adhesions, bowel distention, undiagnosed abdominal disease, abdominal wall infection, hernias or burns, fecal fistula or colostomy, tense ascites, obesity, large polycystic kidneys, recent aortic graft replacement, lactic acidosis and severe pulmonary disease. When assessing peritoneal dialysis as the mode of therapy in such extreme situations, the benefits to the patient must be weighed against the possible complications.

Solutions containing lactate ion should be used with great care in patients with metabolic or respiratory alkalosis. Lactate should be administered with great care in those conditions in which there is an increased level or an impaired utilization of this ion, such as severe hepatic insufficiency.

An accurate fluid balance record must be kept and the weight of the patient carefully monitored to avoid over or under hydration with severe consequences, including congestive heart failure, volume depletion and shock.

Excessive use of DELFLEX® peritoneal dialysis solution with 4.25% dextrose during a peritoneal dialysis treatment can result in significant removal of water from the patient.

Stable patients undergoing maintenance peritoneal dialysis should have routine periodic evaluation of blood chemistries and hematologic factors, as well as other indicators of patient status.

After removing the outer wrap, check for minute leaks by squeezing the container firmly. If leaks are found, discard the solution because the sterility may be impaired. (A small amount of moisture may be present inside the overwrap, which is normal condensation from the sterilization process.)

Serum calcium levels in patients using low calcium concentrations should be monitored and if found to be low, the peritoneal solution in use should be altered to one with a higher calcium concentration.

PRECAUTIONS

General:

Administer only if the solution is clear, all seals are intact, and there is no evidence of leaking. It is important to mix the buffer (mini-bag) and main solutions thoroughly. Administer within 24 hours after mixing. Once solutions are mixed, medication may be added prior to administration.

Do Not Heat In A Microwave Oven

Care should be taken to see that the catheter is inserted completely, since leakage around the catheter, if not controlled, can create edema from subcutaneous infiltration of the dialysis solution. This will also create an inaccurate fluid balance measurement.

Chronic patients that have been stabilized on peritoneal dialysis therapy should have routine evaluation of electrolyte blood chemistries and hematologic factors measured in order to determine the patient's ongoing condition.

Delflex® peritoneal dialysis solutions do not include potassium. Potassium chloride should only be added under the direction of a physician after careful evaluation of both serum and total body potassium.

Check the inner bag for leaks by gently squeezing the bag before removing the outer wrap. If after applying pressure on the bag, leaks are found, do not use this solution since the sterility of the bag may be compromised.

The outer wrap must be removed immediately before use and is provided with a "Tear Open" feature to make removal easy. See detailed instructions in the Directions for Use section.

Aseptic technique must be used throughout the procedure and at its termination in order to reduce the possibility of infection.

Significant loss of protein, amino acids and water soluble vitamins may occur during peritoneal dialysis. Replacement therapy should be provided as necessary.

Laboratory Tests

Serum electrolytes, magnesium, bicarbonate levels and fluid balance should be periodically monitored.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long term animal studies with DELFLEX® peritoneal dialysis solutions have not been performed to evaluate the carcinogenic potential, mutagenic potential or effect on fertility.

Pregnancy: Teratology Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with DELFLEX® peritoneal dialysis solutions. It is also not known whether DELFLEX® peritoneal dialysis solutions can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. DELFLEX® peritoneal dialysis solutions should be given to a pregnant woman only if clearly needed.

Nursing Mothers

Caution should be exercised when DELFLEX® peritoneal dialysis solutions are administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Adverse reactions occurring with administration of peritoneal dialysis include mechanical and solution related problems as well as the results of contamination of equipment or improper technique in catheter placement. Abdominal pain, bleeding, peritonitis, subcutaneous infection around a peritoneal catheter, catheter blockage, difficulty in fluid removal, and ileus are among the complications of the procedure. Solution related adverse reactions might include peritonitis, catheter site infection, electrolyte and fluid imbalances, hypovolemia, hypervolemia, hypertension, hypotension, disequilibrium syndrome and muscle cramping.

If an adverse reaction does occur, institute appropriate therapeutic procedures according to the patient's needs and conditions, and save the remainder of the fluid in the bag for evaluation if deemed necessary.

HOW SUPPLIED

DELFLEX® peritoneal dialysis solutions are delivered in single-dose flexible bags. All DELFLEX® peritoneal dialysis solutions have overfills declared on the container label. The flexible containers have the capacity for drainage in excess of their stated fill volume for ultrafiltration from the patient.

DELFLEX® peritoneal dialysis solutions are available in 3 liter size with the following formulations:

		1.5% Dextrose	
Ca, mEq/L	3.5 (Standard)	3.5 (Standard)	2.5 (Low)
Mg, mEq/L	1.5 (Standard)	0.5 (Low)	0.5 (Low)
		2.5% Dextrose	
Ca, mEq/L	3.5 (Standard)	3.5 (Standard)	2.5 (Low)
Mg, mEq/L	1.5 (Standard)	0.5 (Low)	0.5 (Low)
		4.25% Dextrose	
Ca, mEq/L	3.5 (Standard)	3.5 (Standard)	2.5 (Low)
Mg, mEq/L	1.5 (Standard)	0.5 (Low)	0.5 (Low)

STORAGE CONDITIONS

Store at 25° C (77° F); excursions permitted to 15°-30°C (59°-86°F). See UPS Controlled Room Temperature. Brief exposure to temperatures up to 40°C/104°F may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F).

Keep DELFLEX and all medicines out of the reach of children.

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Patent Pending
Revised 9/2009

DOSAGE AND ADMINISTRATION

DELFLEX® peritoneal dialysis solutions are provided for intraperitoneal administration only. The mode of therapy, frequency of treatment, formulation, exchange volume, duration of dwell, and length of dialysis should be selected by the physician responsible for the treatment of the individual patient.

To avoid the risk of severe dehydration or hypovolemia and to minimize the loss of protein, it is advisable to select the peritoneal dialysis solution with lowest level of osmolarity consistent with the fluid removal requirements for that exchange.

Not for Intravenous Injection. Do not microwave.

Warm solution as directed by your healthcare provider.

Directions for Use

Get Ready

1. Clean work surface.Use aseptic technique.

2. Gather supplies:
- Warmed DELFLEX Neutral pH Peritoneal Dialysis bag
- Prescribed medicine(s), if ordered by your healthcare provider
- Mask

3. Put on mask. Wash your hands.

4. Tear the overwrap across from the slit edge to open. Wipe away any moisture from the bag.
   Inspect DELFLEX Solution Bags:

5. Place the DELFLEX solution set on the work surface. See **Figure A.**

- Squeeze the main solution bag and the mini-bag to check for leaks.
- When squeezing the mini-bag the bag should remain firm and no solution should leak into the main solution bag or from the blue Safe-Lock® connector.

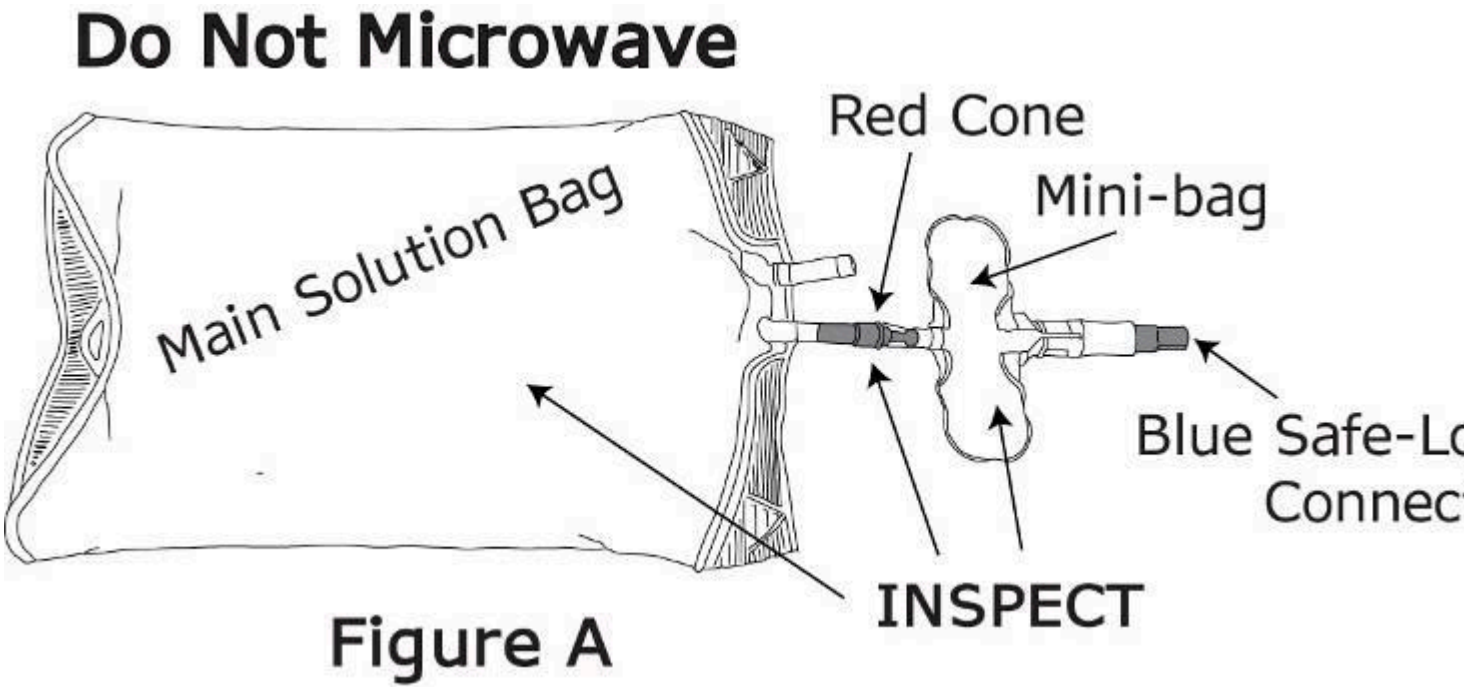

Figure A

Do not use DELFLEX Neutral pH Solution if:

- leaks are found
- the solution bags are damaged
- solution is cloudy or discolored
- Red cone or blue Safe-Lock connector is broken

Throw away DELFLEX Neutral pH Solution and notify your healthcare provider.

Mix DELFLEX® Neutral pH Solution

Important: Mix the mini-bag and main bag solutions thoroughly. Use the solution within 24 hours after mixing.

1. Break the red cone by bending it. See **Figure B.**

Figure B

2. Fold the mini-bag in half. Squeeze the solution from the mini-bag into the main solution bag by pressing the two halves together until the mini-bag is empty. See **Figure C (Step 1).**

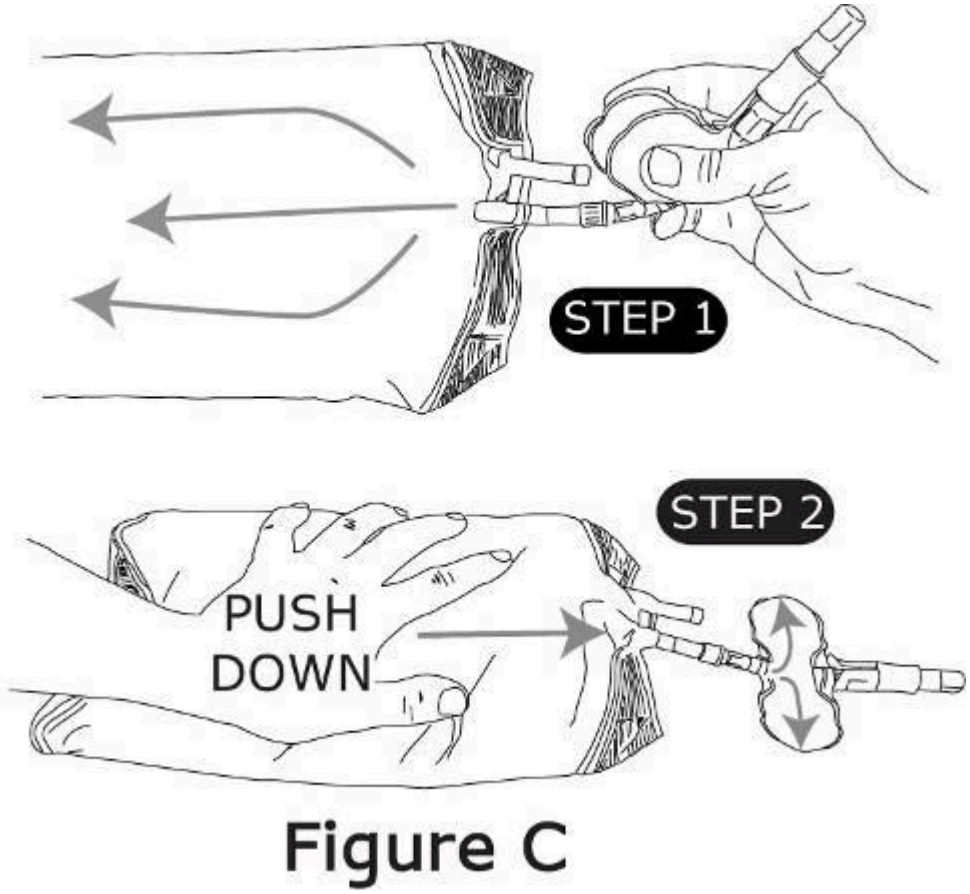

Figure C

3. Push down on the main solution bag to flush solution back into the mini-bag. Completely refill the mini-bag with solution. See **Figure C (Step 2).**

4. Repeat steps 2 and 3 above to make sure that all of the contents of the mini-bag have been completely flushed into the main solution bag.

5. Grab the top of the main solution bag. While keeping the bottom portion of the bag on the table, flip the bag lengthwise using a back and forth motion to mix the solution. See **Figure D**. Repeat to mix solution.

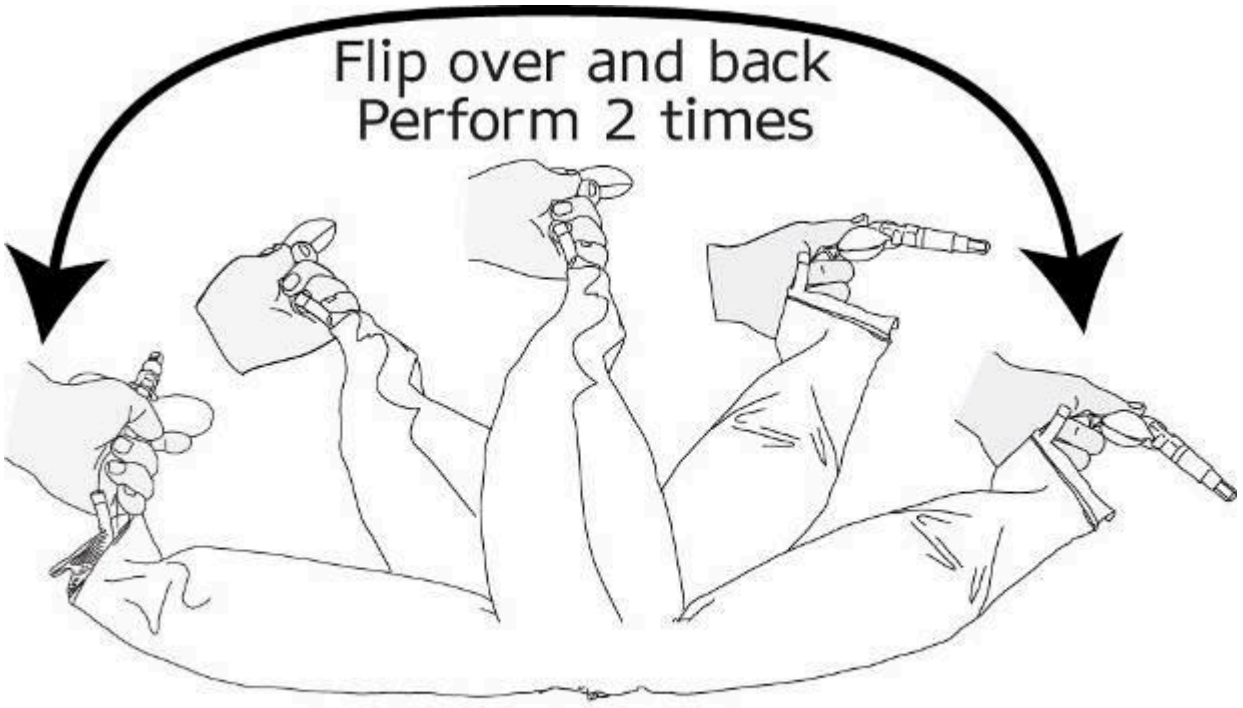

Figure D

6. Fold mini-bag in half and squeeze it empty of solution. Slide the folded mini-bag into the slit of the white cover to show more of the blue Safe-Lock connector. See **Figures E and F.**

The solution is now ready for use.

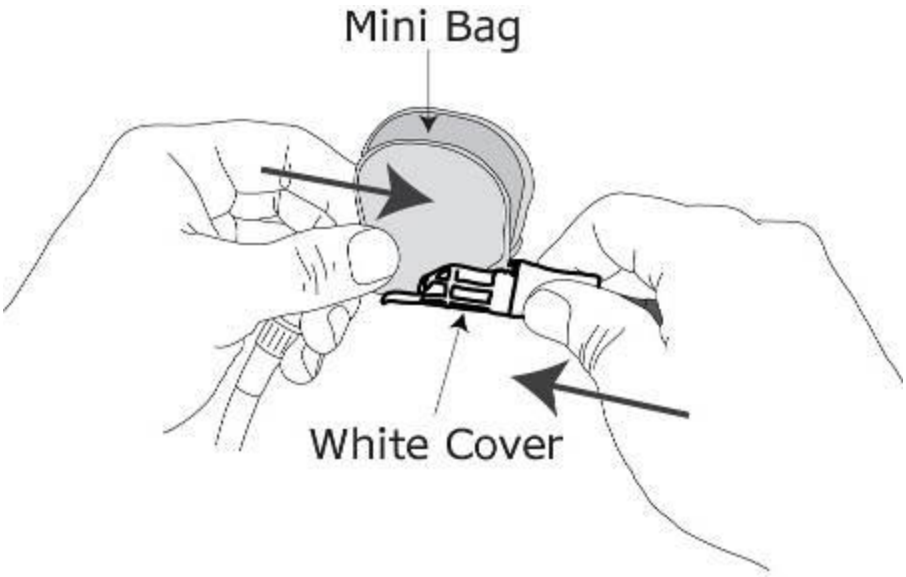

Figure E

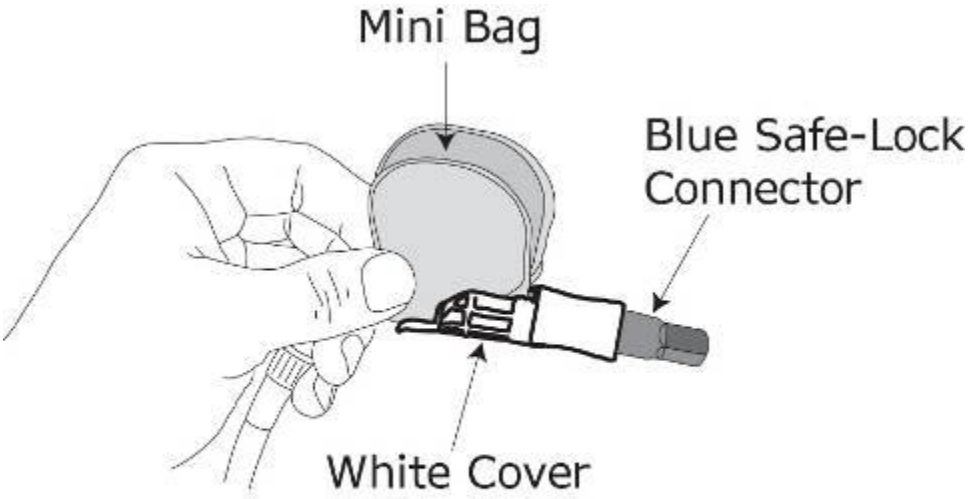

Figure F

Administer Peritoneal Dialysis Solution

1. If you will be adding medicine(s):
- Clean the medication port as instructed by your healthcare provider.
- Add the medicine(s).
- Turn the bag upside down several times to mix the medicine.

2. Take off the protective cap from the blue Safe-Lock® connector at the bottom of the mini-bag. Connect the blue Safe-Lock® connector to mating Safe-Lock connector on the fluid delivery set that is connected to the PD cycler machine.

3. Remove your mask. Do not open the system during fluid exchange.

4. Break the blue Safe-Lock connector tip as shown in **Figure G** to start solution flow.

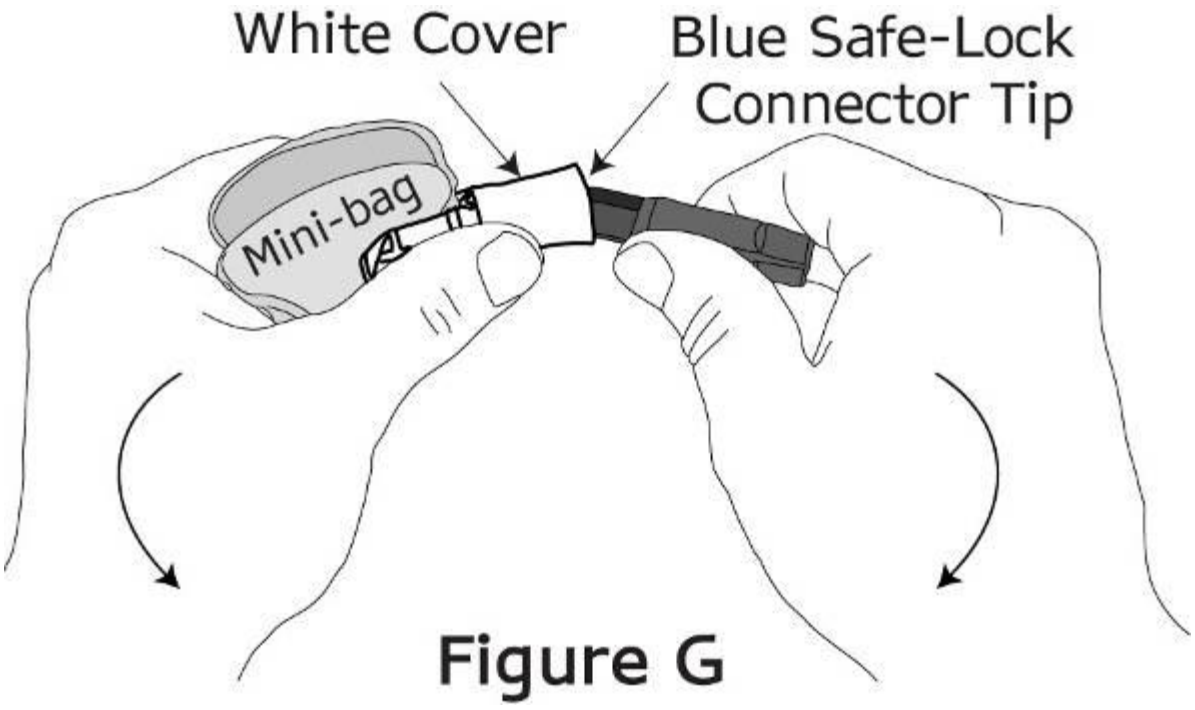

Figure G

5. Look at the drained fluid for cloudiness. Measure the amount of fluid drained. Throw away the fluid and used set as instructed by your healthcare provider. In case of cloudiness, save the fluid and the used set and immediately contact your healthcare provider.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

(01) 003 49230 188 31 8

DELFLEX® Neutral pH
PERITONEAL DIALYSIS SOLUTION
with 1.5% DEXTROSE

CAT. NO. 048-30311 — 3000 mL
NDC 49230-188-31 — (Approx. 60 mL excess)

Values for ingredients listed below as "Combined" reflect the total content AFTER mixing with the mini-bag solution.

Each 100 mL contains:	Combined	Mini-bag	Main Bag
Dextrose Hydrous, USP	1.5 g	-	1.52 g
Sodium Chloride, USP	567 mg	-	576 mg
Sodium Lactate	353 mg	2160 mg	-
Sodium Bicarbonate	29.4 mg	1800 mg	-
Calcium Chloride, USP	25.7 mg	-	26.1 mg
Magnesium Chloride, USP	15.2 mg	-	15.4 mg
Water for Injection, USP	q.s.	q.s.	q.s.
pH	7.0 ± 0.4		

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

APPROXIMATE MILLEQUIVALENTS PER LITER

	Sodium	Magnesium	Bicarbonate	Chloride	Lactate	Calcium
Main Bag	98.6	1.52	-	104	-	3.56
Mini-bag	2142	-	214	-	1927	-
Combined	132	1.5	3.5	102	31.5	3.5

Potassium Chloride to be added only under the direction of a physician.

Sterile. Non-pyrogenic. For Intraperitoneal Administration Only.

Store in outerwrap at 25°C (77°F) until ready for use. See Insert.

Inspect inner bags by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solutions are clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert.

NO LATEX: This product and its packaging do not contain any latex materials.

Read package insert for full instructions
DO NOT HEAT IN MICROWAVE OVEN

Rx only

89-926-22 09/09

Fresenius Medical Care

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Waltham, MA 02451
1-800-323-5188

NDC 49230-188-31 1

DELFLEX® Neutral pH

PERITONEAL DIALYSIS SOLUTION
with 2.5% DEXTROSE

CAT. NO. 048-30312
NDC 49230-191-31

3000 mL
(Approx. 60 mL excess)

Values for ingredients listed below as "Combined" reflect the total content AFTER mixing with the mini-bag solution.

Each 100 mL contains:	Combined	Mini-bag	Main Bag
Dextrose Hydrous, USP	2.5 g	-	2.54 g
Sodium Chloride, USP	567 mg	-	576 mg
Sodium Lactate	353 mg	2160 mg	-
Sodium Bicarbonate	29.4 mg	1800 mg	-
Calcium Chloride, USP	25.7 mg	-	26.1 mg
Magnesium Chloride, USP	15.2 mg	-	15.4 mg
Water for Injection, USP	q.s.	q.s.	q.s.
pH	7.0 ± 0.4		

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

APPROXIMATE MILLEQUIVALENTS PER LITER

	Sodium	Magnesium	Bicarbonate	Chloride	Lactate	Calcium
Main Bag	98.6	1.52	-	104	-	3.56
Mini-bag	2142	-	214	-	1927	-
Combined	132	1.5	3.5	102	31.5	3.5

Potassium Chloride to be added only under the direction of a physician.

Sterile. Non-pyrogenic. For Intraperitoneal Administration Only.

Store in outerwrap at 25°C (77°F) until ready for use. See Insert.

Inspect inner bags by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solutions are clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert.

NO LATEX: This product and its packaging do not contain any latex materials.

Read package insert for full instructions
DO NOT HEAT IN MICROWAVE OVEN

Rx only

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NDC 49230-191-31 1

NDC 49230-194-31 1

DELFLEX® Neutral pH

PERITONEAL DIALYSIS SOLUTION

with 1.5% DEXTROSE

LOW MAGNESIUM

CAT. NO. 048-30301 — 3000 mL

NDC 49230-197-31 — (Approx. 60 mL excess)

Values for ingredients listed below as "Combined" reflect the total content AFTER mixing with the mini-bag solution.

Each 100 mL contains:	Combined	Mini-bag	Main Bag
Dextrose Hydrous, USP	1.5 g	-	1.52 g
Sodium Chloride, USP	538 mg	-	547 mg
Sodium Lactate	409 mg	2500 mg	-
Sodium Bicarbonate	29.4 mg	1800 mg	-
Calcium Chloride, USP	25.7 mg	-	26.1 mg
Magnesium Chloride, USP	5.08mg	-	5.16 mg
Water for Injection, USP	q.s.	q.s.	q.s.
pH	7.0 ± 0.4		

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

APPROXIMATE MILLEQUIVALENTS PER LITER

	Sodium	Magnesium	Bicarbonate	Chloride	Lactate	Calcium
Main Bag	93.5	0.51	-	97.6	-	3.56
Mini-bag	2448	-	214	-	2233	-
Combined	132	0.5	3.5	96	36.5	3.5

Potassium Chloride to be added only under the direction of a physician.

Sterile. Non-pyrogenic. For Intraperitoneal Administration Only.

Store in outerwrap at 25°C (77°F) until ready for use. See Insert.

Inspect inner bags by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solutions are clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert.

NO LATEX: This product and its packaging do not contain any latex materials.

Read package insert for full instructions

DO NOT HEAT IN MICROWAVE OVEN

Rx only

89-926-19 Rev 09/09

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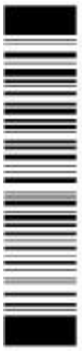

DELFLEX® Neutral pH

PERITONEAL DIALYSIS SOLUTION

with 2.5% DEXTROSE

LOW MAGNESIUM

CAT. NO. 048-30302 — 3000 mL

NDC 49230-200-31 — (Approx. 60 mL excess)

Values for ingredients listed below as "Combined" reflect the total content AFTER mixing with the mini-bag solution.

Each 100 mL contains:	Combined	Mini-bag	Main Bag
Dextrose Hydrous, USP	2.5 g	-	2.54 g
Sodium Chloride, USP	538 mg	-	547 mg
Sodium Lactate	409 mg	2500 mg	-
Sodium Bicarbonate	29.4 mg	1800 mg	-
Calcium Chloride, USP	25.7 mg	-	26.1 mg
Magnesium Chloride, USP	5.08mg	-	5.16 mg
Water for Injection, USP	q.s.	q.s.	q.s.
pH	7.0 ± 0.4		

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

APPROXIMATE MILLEQUIVALENTS PER LITER

	Sodium	Magnesium	Bicarbonate	Chloride	Lactate	Calcium
Main Bag	93.5	0.51	-	97.6	-	3.56
Mini-bag	2448	-	214	-	2233	-
Combined	132	0.5	3.5	96	36.5	3.5

Potassium Chloride to be added only under the direction of a physician.

Sterile. Non-pyrogenic. For Intraperitoneal Administration Only.

Store in outerwrap at 25°C (77°F) until ready for use. See Insert.

Inspect inner bags by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solutions are clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert.

NO LATEX: This product and its packaging do not contain any latex materials.

Read package insert for full instructions

DO NOT HEAT IN MICROWAVE OVEN

Rx only

89-926-20 Rev 09/09

Fresenius Medical Care

Fresenius Medical Care NA
Waltham, MA 02451
1-800-323-5188

NDC 49230-200-31 1

NDC 49230-203-31 1

DELFLEX® Neutral pH

PERITONEAL DIALYSIS SOLUTION

with 1.5% DEXTROSE

LOW MAGNESIUM / LOW CALCIUM

CAT. NO. 048-30321 — 3000 mL

NDC 49230-206-31 — (Approx. 60 mL excess)

Values for ingredients listed below as "Combined" reflect the total content AFTER mixing with the mini-bag solution.

Each 100 mL contains:	Combined	Mini-bag	Main Bag
Dextrose Hydrous, USP	1.5 g	-	1.52 g
Sodium Chloride, USP	538 mg	-	547 mg
Sodium Lactate	409 mg	2500 mg	-
Sodium Bicarbonate	29.4 mg	1800 mg	-
Calcium Chloride, USP	18.4 mg	-	18.7 mg
Magnesium Chloride, USP	5.08 mg	-	5.16 mg
Water for Injection, USP	q.s.	q.s.	q.s.
pH	7.0 ± 0.4		

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

APPROXIMATE MILLEQUIVALENTS PER LITER

	Sodium	Magnesium	Bicarbonate	Chloride	Lactate	Calcium
Main Bag	93.5	0.51	-	96.6	-	2.54
Mini-bag	2448	-	214	-	2233	-
Combined	132	0.5	3.5	95	36.5	2.5

Potassium Chloride to be added only under the direction of a physician.

Sterile. Non-pyrogenic. For Intraperitoneal Administration Only.

Store in outerwrap at 25°C (77°F) until ready for use. See Insert.

Inspect inner bags by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solutions are clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert.

NO LATEX: This product and its packaging do not contain any latex materials.

Read package insert for full instructions

DO NOT HEAT IN MICROWAVE OVEN

Rx only

89-926-25 Rev 09/09

Fresenius Medical Care

Fresenius Medical Care NA
Waltham, MA 02451
1-800-323-5188

NDC 49230-206-31 1

DELFLEX® Neutral pH

PERITONEAL DIALYSIS SOLUTION
with 2.5% DEXTROSE
LOW MAGNESIUM / LOW CALCIUM

CAT. NO. 048-30322 — 3000 mL
NDC 49230-209-31 — (Approx. 60 mL excess)

Values for ingredients listed below as "Combined" reflect the total content AFTER mixing with the mini-bag solution.

Each 100 mL contains:	Combined	Mini-bag	Main Bag
Dextrose Hydrous, USP	2.5 g	-	2.54 g
Sodium Chloride, USP	538 mg	-	547 mg
Sodium Lactate	409 mg	2500 mg	-
Sodium Bicarbonate	29.4 mg	1800 mg	-
Calcium Chloride, USP	18.4 mg	-	18.7 mg
Magnesium Chloride, USP	5.08 mg	-	5.16 mg
Water for Injection, USP	q.s.	q.s.	q.s.
pH	7.0 ± 0.4		

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

APPROXIMATE MILLEQUIVALENTS PER LITER

	Sodium	Magnesium	Bicarbonate	Chloride	Lactate	Calcium
Main Bag	93.5	0.51	-	96.6	-	2.54
Mini-bag	2448	-	214	-	2233	-
Combined	132	0.5	3.5	95	36.5	2.5

Potassium Chloride to be added only under the direction of a physician.

Sterile. Non-pyrogenic. For Intraperitoneal Administration Only.

Store in outerwrap at 25°C (77°F) until ready for use. See Insert.

Inspect inner bags by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solutions are clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert.

NO LATEX: This product and its packaging do not contain any latex materials.

Read package insert for full instructions
DO NOT HEAT IN MICROWAVE OVEN

Rx only

89-926-26 Rev 09/09

Fresenius Medical Care

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NDC 49230-209-31 1

NDC 49230-212-31 1

Revised: 09/2009

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